

JUN 16 2000**Compressor Nebulizer
510(k) Summary****Submitter's Name, Address, Telephone Number and Contact Person****Submitter**

Barry A. Schwartz
Contemporary Products, Inc.
530 Riverside Industrial Pkwy.
Portland, ME 04103
Telephone: 207-797-4647
Facsimile: 207-797-9411
FDA Establishment No.: 1223412

Contact Person

Barry A. Schwartz
Contemporary Products, Inc.
530 Riverside Industrial Pkwy.
Portland, ME 04103
Telephone: 207-797-4647
Facsimile: 207-797-9411

Date Prepared

February 11, 2000

Name of Device

Trade Name: Contempro-Mist
Common Name: Compressor Nebulizer
Classification Name: Nebulizer
21CFR868.5630

Predicate Devices

1. John Bunn Neb-U-Lite II Medication Compressor with Disposable Nebulizer. (K970035)

Intended Use

This nebulizer compressor is an AC-powered air compressor intended to provide a source of compressed air for medical purposes for use in home health care. This device is used in conjunction with a pneumatic nebulizer to produce a fine aerosol mist of medication for respiratory therapy, for both children and adults suffering from respiratory disorders such as asthma allergies etc.

Technological Characteristics and Substantial Equivalence

This piston-driven nebulizer contains vents in the two sides and bottom of the case providing ventilation for the motor. The compressor has only one control-a double pole toggle switch to turn the compressor on and off. The unit has a two-wire power cord with a polarized plug, an internal fuse, and no

exposed metal that is likely to become energized (two screws that hold the case together are greatly recessed on the bottom surface and are not likely to become energized). In use the compressor is placed on a flat surface and the cover is opened to reveal an outlet hose barb to which the oxygen (air) delivery tubing and nebulizer are connected. Inlet air to the compressor passes through a replaceable filter.

Distributed with the device will be nebulizers purchased from the following company:

Hudson RCI, Temecula, CA 02589-9020, Model: Micro Mist® Code 41892.

Both devices are AC-powered, contain the same filter material, meet UL 1431 and are in the same compressor operating pressure and liter flow ranges. Performance characteristics are identical.

Performance Data

Compressor Pressure:	30 PSI
Min. residual pressure w/ ampul:	10 PSI
Min. compressor free air flow:	8 LPM

Standards applied:	U.L. 1431, CSA/CAN-C22.2-68-92
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Further, the Contempro-Mist device is identical in all manners to the predicate device and is manufactured by the same company.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 16 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Barry A. Schwartz
President
Contemporary Products, Inc.
530 Riverside Industrial Pkwy.
Portland, ME 04103

Re: K000543
Contempro-Mist Compressor
Regulatory Class: II (two)
Product Code: 73 CAF
Dated: April 6, 2000
Received: April 7, 2000

Dear Mr. Schwartz:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

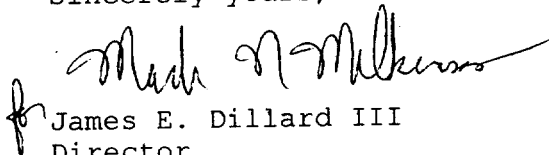
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. Barry A. Schwartz

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Contemporary Products, Inc.
Medication Compressor with Disposable Nebulizer

Indications for Use Statement

510(k) Reference Number:

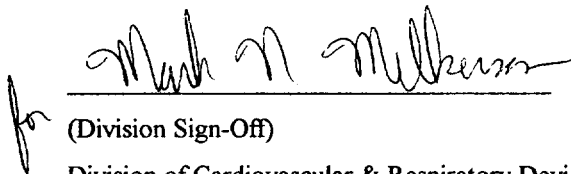
This is an initial submission; no number has yet been assigned.

Statement of Indications for Use:

This nebulizer compressor is an AC-powered air compressor intended to provide a source of compressed air for medical purposes for use in home health care. This device is used in conjunction with a pneumatic nebulizer to produce a fine aerosol mist of medication for respiratory therapy, for both children and adults suffering from respiratory disorders such as asthma allergies etc.

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED.)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)


(Division Sign-Off)

Division of Cardiovascular & Respiratory Devices
Anesthesiology and Defibrillator Devices Branch

510(k) Number: K000543

Prescription Use ✓

OR

Over-the Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)